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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,865	07/31/2001	Gideon Strassmann	116-039	2422

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,865	Applicant(s) STRASSMANN ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8-10 and 13-17 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 and 21 is/are allowed.
- 6) ☒ Claim(s) 6, 7 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|---|--|

Pursuant to the directives of the response filed 6/18/04, claims 6 and 18 have been amended, claims 11-12 cancelled, and claims 19-21 added.

Claims 1-10, 13-21 are pending; claims 1-5, 8-10, 13-17 remain withdrawn from consideration. Applicants' arguments filed 6/18/04 have been considered and found persuasive in part. The rejection of claim 18 under 35 U.S.C. §112 first paragraph is withdrawn. Claims 20-21 are characterized as allowable at the present time.



Claims 6, 7, and 18-19 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 18 is drawn to a method which comprises administering a compound of claim 6. Thus, claim 18 implies that claim 6 is drawn to a compound *per se*. As it happens, however, claim 6 is not drawn to a compound *per se*. Rather, claim 6 is drawn to a method. Furthermore, the method of claim 6 is not the same as the method of claim 18. Accordingly, the claim dependence is not proper. One option would be to write claim 18 in independent form.
- The claims are indefinite as to the criteria that are to be used in deciding whether a bird has a disease, and if so, whether it is of sufficient impact to warrant exclusion of the bird from the claimed method. For example, suppose that a bird suffers a minor viral infection from which it recovers within a few days. Is this bird intended to be excluded from the claims? What if the bird is asymptomatic (e.g., col 4, line 47, Lowenthal)...?
- Claim 19 is drawn to a method "for feeding for enhancing...". However, the only process step that is recited is administration of the cited tellurate compound.

There is no mention of food or a feed material, and no explanation of how the skilled artisan would go about achieving "feeding" by administering the tellerate compound. Thus, it would appear that the claim is incomplete, or that process steps are missing.



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 5,475,030).

As indicated previously, Sredni discloses (col 5, line 51+) various tellurium compounds that are asserted to be useful for treatment of cancer, immune deficiencies, autoimmune diseases and infectious diseases. Sredni does not disclose that animals which are afflicted with one or more of the foregoing diseases can experience weight loss. However, it is

known to veterinarians of ordinary skill that animals (including birds) which are stricken with cancer, immune deficiencies, autoimmune diseases or infectious diseases will often suffer a weight loss. Thus, it would have been obvious to one of ordinary skill at the time of the invention that if one of the tellurium compounds of Sredni is administered to an underweight bird that is stricken with cancer, an immune deficiency, an autoimmune disease or an infectious disease, the bird will gain weight if the compounds are effective to eradicate the bird's illness as asserted in the '030 patent.

In response to the foregoing, applicants have taken issue with the examiner's use of the term "fully grown" to describe one category of bird. Applicants have argued that one interpretation of the term "fully grown" is that no further growth is possible. Perhaps it is possible to interpret the term in this way, but that is not the way the term is generally used. One can start by discussing how the term is used when applied to humans. A human could legitimately be described as being "fully grown" by the time that he reaches the age of 20. Yet as applicants are no doubt aware, it is quite common for the weight of a human to be greater at e.g., age 50 than at age 20, despite the fact that no further skeletal growth has occurred. Generally this weight gain is due to the greater presence of adipose tissue in the age 50 subject as compared to the age 20 subject. Or consider the case of a person who is "fully grown" at age 20, and subsequently decides to self administer anabolic steroids or growth hormone secretagogues for the purpose of increasing muscle mass, perhaps accompanied by a rigorous exercise program. The point here is that applicants have

misconstrued the meaning of the term “fully grown”. This term does not mean that no further growth is possible, only that further weight gain, apart from adipose tissue, is not genetically predetermined.

Returning at hand to the issue of birds and their weight as a function of various factors, the term “fully grown” was never intended to mean that no further weight gain was possible. If one took a “fully grown” bird, one could expect to achieve weight gain (in the “fully grown” bird) through appetite stimulants, hormones which stimulate growth of muscle, or by increasing the fat content of the food. Accordingly, applicants suggestion that it is impossible for a “fully grown” bird to gain weight is not correct.

Applicants have also argued that the claim language is such as to preclude birds that have been stricken with a disease. However, the claims are drawn to a method for enhancing weight gain in poultry. There is no proviso which recites that if the bird has been stricken with a flu virus or a gastrointestinal bacteria or a fungal infection in the lung, that such a bird is to be excluded from the claims. As a practical matter, one would expect that out of a population of, e.g., 1000 chickens, at least one would be infected with a bacteria or virus at some point in its life. Most such infections do not lead to a shortening of the bird’s life; many such infections do not lead to any obvious symptoms. There is nothing in the claims to suggest that a bird with a minor flu infection (for example) should be excluded. As such, all birds are encompassed.

Thus, applicants have attempted to “define away” the reality that fully grown birds can gain

weight under certain circumstances, and to argue that the claims exclude birds in which the slightest infection could be detected, were one motivated to look for such evidence. However, applicants are incorrect on both points. The rejection is maintained.



Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 5,126,149) or Albeck (USP 4,761,490) in view of Lowenthal (USP 6,642,032).

Sredni and Albeck both teach that tellurium compounds are effective to promote production of lymphokines. Such lymphokines include (col 1, line 42, Albeck) *gamma* interferon. Neither of Sredni or Albeck disclose that an effect of increasing production of *gamma* interferon is to promote weight gain in birds. Lowenthal discloses that *gamma* interferon promotes weight gain in birds. Thus, it would have been obvious to one of ordinary skill that administering an organotellurium compound to a bird will result in weight gain.

Applicants' data on page 15 (specification) is noted. Consider also that the claims encompass the following four categories of invention:

- (a) juvenile birds in a rapid growth phase, wherein the birds are healthy;
- (b) juvenile birds in a rapid growth phase, wherein the birds are unhealthy;
- (c) fully grown adult birds that are healthy;
- (d) fully grown adult birds that are unhealthy.

If one stipulates that the data on page 15 qualify as "unexpected", the data would serve to render novel only the first of the four categories of invention. This ground of rejection primarily targets categories (b), (c) and (d), for which there are no "unexpected results".

In response to the foregoing, applicants have argued that because Lowenthal suggests i.p. administration of interferon, the skilled veterinarian would believe that the agent which promotes production of the interferon should also be administered in this way. It is noted that Lowenthal suggests (col 25, line 67) adding an interferon-producing agent to animal feed, although this rejection does not rely on this disclosure. The point is that it is the tellurium compound of Sredni that is being administered, not the interferon. The interferon is produced as a consequence of the administration of the tellurium compound of Sredni. Thus, even if Lowenthal had specifically stated that the interferon would fail to be effective if administered in animal feed, this would not in any way undermine the validity of the rejection. This is because, again, what is obvious is not the administration of interferon itself, but rather an agent which promotes production of interferon. Accordingly, what matters is the modes of administration of the tellurium compound, not the modes of administration of the interferon.

Certainly, the veterinarian of ordinary skill would be well acquainted with routes of administration of various agents. Perhaps if a single turkey or goose were at issue, it might make sense to inject a compound into the animal. But for the farmer with 1000 chickens, it doesn't require a degree in veterinary medicine to recognize the economics of individually injecting all of those chickens individually, *versus* simply adding the tellurium compound to

the feed.

With respect to the four categories of birds recited by the examiner (above), applicants have argued that neither reference lists such categories, and that therefore it follows that three of the four categories should be excluded from the claims. However, the fact that neither reference lists the categories of birds is largely irrelevant. What matters is what the claims encompass. A bird is a bird. A healthy bird is a bird. An unhealthy bird is a bird. A young bird is a bird. An old bird is a bird. The same analysis applies to humans. Surely applicants would not argue that if a person catches a minor cold, he is not longer human. Nor would applicants argue that persons cease to be human after their 60th birthday. Similarly, the instant claims encompass birds that are young and healthy, birds that have been stricken with a minor illness, birds that have been stricken with a major illness, birds that are thin, birds that are fat, birds with an above average appetite, birds with a below average appetite, birds in which the skeletal structure is fully developed, birds that in which the skeletal structure is not fully developed, birds that cannot fly, large birds, and small birds. Applicants' argument that the claims exclude certain categories of birds is found entirely unpersuasive. Furthermore, even if, as a hypothetical matter, the claims were amended to recite that birds with certain specific symptoms of disease are to be excluded, the rejection could still be maintained, as Lowenthal suggests (col 4, line 47) using his invention even if the bird is asymptomatic. The rejection is maintained.



Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 4,929,739)

Sredni discloses that complexes of tellurium and selenium are effective to treat cancer and immunodeficiency. Sredni does not disclose that animals afflicted with cancer or immunodeficiency often suffer weight loss. However, this is known to the veterinarian of ordinary skill. Moreover, such weight loss is going to be inevitable for animals that must hunt for food. Thus, the veterinarian of ordinary skill would have expected that by administering the disclosed complexes of tellurium and selenium to an underweight animal (e.g., a bird) that is afflicted with cancer or immunodeficiency, the health of the animal will be restored, and normal weight realized.

In response to the foregoing, applicants have argued that somewhere in the claims, there is a proviso which excludes any bird that has a minor infection or other illness. However, the location of this proviso is not apparent, and applicants have not identified the location in the text where it may be found. In response to this rejection it is suggested that applicants point out the location of the proviso, or in the alternative, provide some authority for the proposition that a bird ceases to be a bird if it develops an illness, however minor it may be.

The rejection is maintained.



Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 4,929,739) in view of Lowenthal (USP 6,642,032).

Sredni discloses that complexes of selenium and tellurium are effective to promote production of lymphokines. Such lymphokines would include *gamma* interferon. Sredni does not disclose that an effect of increasing production of lymphokines is to promote weight gain in birds. Lowenthal discloses that a lymphokine (*gamma* interferon) promotes weight gain in birds. Thus, it would have been obvious to one of ordinary skill that administering an organotellurium or organoselenium compound to a bird will result in weight gain.

Applicants have argued that a skilled veterinary specialist would not realize that medication can be added to animal feed. However, this is found to be unpersuasive. The level of knowledge of a veterinarian goes far beyond this simple concept. Furthermore, economic reality would force any farmer to consider administration of a medication via the feed, as opposed to individual injection of every bird in his possession.

The rejection is maintained.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LINTON
PATENT EXAMINER
GROUP 1800